

REMARKS

In the application claims 24-33 and 42-50 remain pending. No additional claims have been canceled. Claim 24 has been amended. Support for the amendment may be found in the specification, claims, and figures as originally filed. No new matter has been added.

Pending claims 24-26, 32, 42-45, and 50 presently stand rejected. The reconsideration of the rejection of the claims is respectfully requested. Furthermore, since generic claim 24 should be found to be allowable, it is respectfully submitted that claims 27-31, 33, and 48 must be reinstated into the subject application for patent.

More particularly, claims 24-26, 32, 42-45, and 50 stand rejected as being anticipated or rendered obvious by Vardi (U.S. Patent No. 6,210,429). In rejecting the claims, the Office Action set forth that Vardi disclosed a main member (12), a side-branch member (15), a delivery system including a main guidewire (20), a side-branch guidewire (36), a main balloon catheter (48), and a side-branch balloon catheter (54). With respect to the connection between the main member (12) and the side-branch member (15), the Office Action asserted that, in the deployment configuration, the main member (12) and the side-branch member (15) are “integrally connected because the main member (12) and the side-branch member (15) each is an essential or necessary constituent/element of the complete device.”

Alternatively, the Office Action set forth that “it would have been obvious to one of ordinary skill in the art ...to make the main member (12) and branch-side member (15) integrally connected or bonded, since it has been held that forming in one piece an article which has formally been formed in two pieces and put together involves only routine skill in the art.”

In response to these rejections of the claims, it is respectfully submitted that a rejection under 35 U.S.C. §§ 102 or 103 requires that each and every element set forth in the claims, considering each and every word, be found, either expressly or inherently, in the reference(s) being relied upon. To be “inherently” described in a prior art reference, the prior

art reference “must make clear that the missing descriptive matter is necessarily present in the thing described and that it would be so recognized by persons of ordinary skill.” Inherency “may not be established by probabilities or possibilities.” The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

Turning to Vardi, it is first respectfully submitted that, while Vardi may disclose a main member (12) and a side-branch member (15), Vardi fails to disclose, teach, or suggest at least the claimed main member comprising a wall having an opening and at least one side-branch member having a proximal end which is both integrally connected to the main member at the opening and disposed within the main member at a time prior to insertion of the main member into the vessel, wherein the at least one side-branch member is configured and arranged within the main member at a time prior to insertion of the main member into the vessel to allow the at least one side-branch member to be extended from within the main member through the opening. Rather, Vardi describes and illustrates a stent apparatus wherein the side-branch member (15) is constructed as a component that is separate and distinct from the main member (12) and which is inserted into the main member (12) at a time after the main member (12) is inserted into a vessel. As expressly set forth in Vardi, and clearly illustrated in Figs. 6a – 6g, the side-branch member (15) is not integrally connected to the main branch member (12) at a time prior to the insertion of the main branch member (12) into a vessel and does not even contact the main branch member (12) until after the side-branch member (15) is inserted through a side opening (16) of the main member (12) and then inflated to an expanded position. Thus, since Vardi fails to disclose, teach, or suggest at least the aforementioned claim elements, Vardi cannot be said to anticipate the invention claimed and the rejection of the claims must be withdrawn.

While the Office Action has asserted that it would have nevertheless been obvious to modify Vardi to arrive at the invention claimed since it would involve “only routine skill in

the art” to form the device of Vardi as a one piece article, it is respectfully submitted that case law has established that, where the claimed invention shows insight that is contrary to the understanding and expectation of the prior art, it is not merely a matter of obvious engineering choice to “use a one piece construction.” *Schenck v. Norton Corp.* 713 F.2d 782 (Fed. Cir. 1983). Since the invention claimed is, in fact, contrary to the understanding and expectation of Vardi which describes that it is essential that the disclosed device be constructed so as to utilize a side-branch member that is separate and distinct from the main branch member for the reason that it allows for the “treat[ing] of lesions in one branch of a bifurcation while preserving complete access to the other branch for future treatment” and allows for “a bifurcating double-stent device wherein the main stent and the branch stent or stents may be of different sizes,” it is respectfully submitted that a *prima facie* case of obviousness has not been established. Still further, it is respectfully submitted that the proposed modification of Vardi set forth in the Office Action fails to present a *prima facie* case of obviousness for the reason that the modification espoused in the Office Action would change the very principle of operation of the device of Vardi and it is well settled that, if a proposed modification of a device changes the principle of operation of the device being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810 (CCPA 1959). Still further, it is respectfully submitted that, even if one were to accept that it is a merely a matter of engineering choice to form the device of Vardi as a one piece article (which it is not), there still remains no teaching or suggestion with respect to the claimed configuring and arranging the side-branch member within the main member at a time prior to insertion of the main member into the vessel to allow the at least one side-branch member to be extended from within the main member through the opening. For each of these reasons, it is respectfully submitted that the rejection of the claims in view of Vardi must be removed.

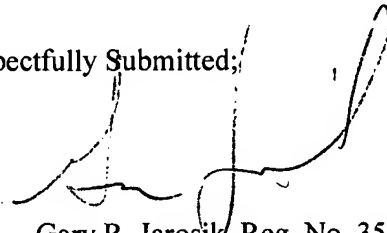
With respect to the remaining claim elements, it is once again respectfully submitted that the mere fact that the Vardi apparatus is provided to support a blood vessel does not make clear that the main member or the side-branch member necessarily is biocompatible, circumferentially distensible *with* minimal foreshortening, has low recoil, or is kink resistant and that it would be so recognized by persons of ordinary skill. Rather, since the Vardi stent apparatus could support a blood vessel without having any of these claimed features, it is submitted that Vardi cannot be said to inherently disclose the missing claim elements and the rejection of the claims must be withdrawn.

CONCLUSION

The subject application is considered to be in condition for allowance. Such action on the part of the Examiner is respectfully requested. Should it be determined, however, that a telephone conference would expedite the prosecution of the subject application, the Examiner is respectfully requested to contact the attorney undersigned.

While it is not believed that any fees are due, the Commissioner authorized to charge any fee deficiency to deposit account number 50-2428.

Respectfully Submitted;



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